UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,335	12/12/2003	Doddabele L. Madhavi	BIO 2-016	3791

7590 07/26/2005

Jerry K. Mueller, Jr.
Mueller and Smith, LPA
7700 Rivers Edge Drive
Columbus, OH 43235

EXAMINER	
FEDOWITZ, MATTHEW L	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,335	MADHAVI ET AL.	
	Examiner	Art Unit	
	Matthew L. Fedowitz	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are pending in this action.

Provisional Obviousness Double Patenting

As stated in the office action dated March 14, 2005, claims 1-3, 5-7, 9-13, 15-17 and 19-20 were rejected under double patenting. These claims remain rejected for the reason stated in section C below. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting grounds provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The applicant claims that the unexpected discovery that the commercial method of drying and formulation impacts the bioavailability of the of lutein from a lutein/cyclodextrin complex and that the process can be adapted to other carotenoids. This argument is found to be persuasive

with regard to bioavailability of lutein and γ-cyclodextrin through the disclosure of a side-by-side comparison between spray dried and freeze dried formulations but is not persuasive with regard to all cyclodextrins and adaptations to other carotenoids because no side-by-side comparison to the other cyclodextrins claimed are disclosed nor are there any side-by-side comparisons between freeze dried and spray dried formulations with other carotenoids.

Moreover, the unexpected discovery of increased bioavailability would possess greater weight if the claims were drawn to a method of increasing bioavailability rather than composition and method of making claims.

The applicant then states, through declaration, that the third inventor on the USSN '999 application only contributed the polymer coatings that were applied to the complex. The applicant also claims that which Doddabele Madhavi and Daniel Kagan are responsible for in the published application. Doddabele Madhavi and Daniel Kagan are responsible for a coating described as oil from vegetable sources as stated in claim 3. Therefore the claims attributed to the third inventor are considered to be commensurate in scope to those attributed to Doddabele Madhavi and Daniel Kagan.

The applicant further states that no difference in drying was known to the USSN '99 inventors and that spray drying was only reduced to practice. This statement is not persuasive because the USSN '999 applicant states in paragraph 19 freeze-drying and spray drying may be employed to dry the complexes.

The applicant also states that the vegetable oil employed increases bioavailability, however, once again the applicant is reminded that the weight of this disclosure would be greater

if the claims were directed to a method of increasing bioavailability rather than composition and method of making claims.

The applicant then states that it is not understood what is meant by the Examiner's statement regarding not addressing the claims individually where the rejection is based on a combination of references. Applicant is reminded that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The Examiner has applied the references in combination where office policy is to follow Graham v. John Deere Co. in the consideration and determination of obviousness under 35 U.S.C. 103 (see MPEP 2141). As such, a combination of references has been used and the applicant must address the combination as group and not individually.

The applicant also "takes issue" with the examiner's consideration of Doddabele Madhavi's and Daniel Kagan's declaration. The applicant should be aware that Doddabele Madhavi's and Daniel Kagan's education is not relevant to the facts at hand; furthermore, Doddabele Madhavi's and Daniel Kagan's experience, among others, in providing a "midcourse evaluation of novel technology" or "completing 75% of MBA courses" is not relevant to the to the claims at hand. Weight is assigned to factual data of side-by-side comparisons and has been considered. The weight that was assigned was considered in that it was directed, among other areas, to elucidating the increased bioavailability; however, the claims are directed to compositions and methods of making complexes disclosed in the prior art and NOT to claims directed to methods of increasing bioavailability. In addition, the arguments based on the

expert's opinions have been assigned weight commensurate in scope with that of any expert with and interest in the outcome of the case (see MPEP 716.01(c)).

Therefore, in light of the prior art, directed to the claimed COMPOSITONS and METHODS OF MAKING, the applicant's arguments are found to be unpersuasive when considered as a whole. Furthermore, the applicant should be aware that the mere submission of evidence does not mandate a conclusion of patentability in and of itself. In re Chupp. 816 F.2d 643, 2 USPQ2d 1437 (Fed. Circ. 1987)

Claim Rejections - 35 USC § 103

As stated in the office action dated March 14, 2005, claims 1-20 were rejected under 35 USC § 103. The applicant arguments and declarations have been fully considered and are not found to be persuasive for the reasons stated in the rejection dated March 14, 2005 and for the reasons stated above when the case is considered as a whole

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew L. Fedowitz whose telephone number is (571) 272-3105. If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew L. Fedowitz, Pharm.D., Esq.

James O. Wilson, Supervisory Patent Examiner
Art Unit 1623